



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1682]

Ursula Wing: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Ursula Wing for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Ms. Wing was convicted of one felony count under Federal law for conspiracy to defraud the United States. Ms. Wing was given notice of the proposed debarment and an opportunity to request a hearing to show why she should not be debarred within the timeframe prescribed by regulation. Ms. Wing failed to request a hearing. Ms. Wing's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance. On July 10, 2020, Ms. Wing was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Western District of Wisconsin, when the court accepted her plea of guilty and entered judgment against her for the felony offense of conspiracy to defraud the United States in violation of 18 U.S.C. 371.

FDA's finding that debarment is appropriate is based on this felony conviction referenced herein. The factual basis for this conviction is as follows: as contained in count 1 of the indictment in Ms. Wing's case, filed on June 26, 2019, to which she pleaded guilty, from in or about June 2016 and continuing to on or about June 21, 2018, she operated a blog under the name "the Macrobiotic Stoner" and a fake jewelry business under the name "Morocco International Inc." Ms. Wing used both entities to sell unapproved and misbranded prescription drugs to consumers in the United States and around the world and to process payments for those drugs. Throughout the course of this conspiracy Ms. Wing did not possess a valid wholesale drug distribution license, pharmacy license, or a license to prescribe prescription drugs. She was also not registered under section 510 of the FD&C Act (21 U.S.C. 360) as a person who owns or operates an establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug.

As part of this conspiracy, Ms. Wing imported foreign-sourced prescription drugs in wholesale quantities from India into the United States. The imported drugs contained U.S. Customs Declaration Forms falsely stating that the contents were "personal supply medication" and did not contain any dangerous articles or articles prohibited by postal or customs regulations. The drugs Ms. Wing imported were foreign versions of mifepristone and misoprostol. There are two 200 mg mifepristone tablets that are FDA-approved for use in a regimen with misoprostol

for the medical termination of early pregnancy. There are no approved drug applications pursuant to section 505 of the FD&C Act (21 U.S.C. 355) in effect for the mifepristone and misoprostol Ms. Wing imported and sold via her website. In addition to being unapproved, the drugs sold via Ms. Wing's website were also misbranded because they failed to bear adequate directions for their intended use (see 21 U.S.C. 352(f)(1) and 21 CFR 201.5) and are prescription medications that were dispensed without a prescription from a practitioner licensed by law to administer such drugs (21 U.S.C. 353(b)(1) and 331(k)).

Ms. Wing broke down the bulk shipments of unapproved and misbranded drugs she received from India and repackaged them into retail quantities which she then shipped to customers in the United States and around the world via U.S. mail. To disguise her sales, Ms. Wing created a fake company called "Fatima's Bread Basket," which she listed as the shipper on the envelope going to the customer. Ms. Wing then inserted a piece of jewelry in the shipping envelope to serve as the cover piece of merchandise being mailed to the customer. She packaged the unapproved and misbranded prescription drugs in a smaller packet that was in a hidden panel and taped to the inside of the shipping envelope. Ms. Wing disguised the nature of the item being purchased by listing on the invoice alternate jewelry product names, each of which had a code to indicate the actual item (unapproved and misbranded drug(s)) being ordered.

As a result of this conviction, FDA sent Ms. Wing, by certified mail on October 15, 2020, a notice proposing to debar her for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Ms. Wing's conviction for one felony count under Federal law, for conspiracy to defraud the United States, was for conduct relating to the importation into the United States of any drug or controlled substance because she illegally smuggled unapproved and misbranded prescription drugs from India into the United States and then distributed those misbranded and unapproved drugs to consumers both in the United States and abroad.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Ms. Wing's offense, and concluded that this felony offense warranted the imposition of a 5-year period of debarment. The proposal informed Ms. Wing of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Wing received the proposal and notice of opportunity for a hearing on October 19, 2020. Ms. Wing failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Ursula Wing has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Ms. Wing is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Ms. Wing is a prohibited act.

Any application by Ms. Wing for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2020-N-1682 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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